UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF ILLINOIS

:

IN RE YASMIN AND YAZ (DROSPIRENONE) MARKETING, SALES PRACTICES AND RELEVANT PRODUCT LIABILITY LITIGATION

TIMBERLEY CHRISTIE

Plaintiff,

v.

BAYER CORPORATION, an Indiana corporation; 100 Bayer Road Pittsburgh, PA 15205,

BAYER HEALTHCARE
PHARMACEUTICALS, INC.,
a Delaware corporation,
6 West Belt Road
Wayne, NJ 07470,

BAYER HEALTHCARE, LLC, a Delaware corporation, 555 White Plains Road Tarrytown, NY 10591,

BAYER SCHERING PHARMA AG, Müllerstrasse 178 D-13353 Berlin Germany,

Defendants.

: 3:09-md-02100-DRH-PMF

MDL NO. 2100

Judge David R. Herndon

FIRST AMENDED COMPLAINT AND JURY DEMAND

Civil Action No. 3:09-CV-20100-DRH-PMF

Plaintiff, TIMBERLEY CHRISTIE, by and through her counsel, and for her Complaint against Defendants, alleges as follows:

PARTIES AND JURISDICTION

- 1. Plaintiff is a resident and citizen of LaPorte, Texas located in Harris County.
- 2. Plaintiff was prescribed and ingested Yaz in the State of Texas, and while using Yaz, she suffered a deep vein thrombosis in or about November 2007, in the State of Texas.
- 3. Plaintiff alleges an amount in controversy in excess of Seventy-Five Thousand Dollars (\$75,000.00), exclusive of interest and costs.
- 4. Defendant Bayer Corporation is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205. Defendant Bayer Corporation is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drugs Yasmin and Yaz. At all relevant times, Defendant Bayer Corporation conducted regular and sustained business in Texas by selling and distributing its products in Texas and engaged in substantial commerce and business activity in Harris County.
- 5. Defendant Bayer Healthcare Pharmaceuticals, Inc. is a Delaware corporation, with its principal place of business at 6 West Belt Road, Wayne, New Jersey 07470. Bayer Healthcare Pharmaceuticals, Inc. was created by the integration of Bayer Healthcare and Berlex Laboratories. Defendant Bayer Healthcare Pharmaceuticals, Inc. is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drugs Yasmin and Yaz. At all relevant times, Defendant Bayer Healthcare Pharmaceuticals, Inc. conducted regular and

sustained business in Texas by selling and distributing its products in Texas and engaged in substantial commerce and business activity in Harris County.

- 6. Defendant Bayer Healthcare, LLC is a Delaware limited liability company, with its principal place of business at 555 White Plains Road, Tarrytown, New York 10591. Bayer Healthcare, LLC was involved in the integration of Bayer Healthcare and Berlex Laboratories. Defendant Bayer Healthcare, LLC is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drugs Yasmin and Yaz. At all relevant times, Defendant Bayer Healthcare, LLC conducted regular and sustained business in Texas by selling and distributing its products in Texas and engaged in substantial commerce and business activity in Harris County.
- 7. Bayer Schering Pharma AG, formerly known as Schering AG, is a pharmaceutical company that is organized and existing under the laws of the Federal Republic of Germany, having a principal place of business at Müllerstrasse 178, 13353 Berlin, Germany. At all relevant times, Bayer Schering Pharma AG was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive Yaz and Yasmin.
- 8. Defendants Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, and Bayer Schering Pharma AG are collectively referred to herein as "Bayer" or "Defendants."

- 9. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332 because there is complete diversity of citizenship between the parties, and the amount in controversy exceeds \$75,000.00, exclusive of interest and costs.
- Venue is proper in this District and in this Court in accordance with MDL 2100Case Management Order No. 9, allowing direct filing of this action in this District.

FACTUAL BACKGROUND

Nature of the Case

11. Plaintiff brings this case against Defendants for damages associated with her ingestion of the pharmaceutical drug Yaz, an oral contraceptive designed, manufactured, supplied, marketed, and distributed by Defendants. Specifically, Plaintiff was diagnosed with a deep vein thrombosis in November 2007, as a direct result of her use of Yaz.

<u>Bayer's Combined Oral Contraceptives – Yasmin and Yaz</u>

- 12. Yasmin and Yaz are birth control pills manufactured and marketed by Bayer. They are combination oral contraceptives, or "COCs," meaning that they contain an estrogen component and a progestin component. Together, these steroidal components work together in COCs to suppress ovulation, fertilization, and implantation and thus prevent pregnancy.
- 13. Yasmin and Yaz were approved by the Food and Drug Administration for marketing in 2001 and 2006 respectively.

Yasmin and Yaz Contain a "Fourth Generation" Progestin

14. The estrogen component in Yasmin and Yaz is known generically as ethinyl estradiol. The progestin component is known as drospirenone. Yasmin contains 0.03 milligrams of ethinyl estradiol, and Yaz contains 0.02 milligrams of ethinyl estradiol. Both products contain 3 milligrams of drospirenone.

- 15. Yasmin and Yaz are different from other combined hormonal birth control pills in that they contain drospirenone, a progestin that is unlike other progestins available in the United States and was never before marketed in the United States prior to its use in Yasmin.
- 16. Shortly after the introduction of combined oral contraceptives in the 1960's, doctors and researchers found that women using birth control pills had a higher risk of blood clots, heart attacks, and strokes than women not using the pill. As a result, the various brands of birth control pills were reformulated to reduce the amounts of estrogen. As the amounts of estrogen levels reduced, so too did the risk of blood clots, heart attacks, and strokes.
- 17. During this time, new progestins were being developed, which became known as "second generation" progestins (e.g. lovenorgestrel). These second generation progestins, when combined with the lower amounts of the estrogen, ethinyl estradiol, helped to reduce the risk of blood clots, heart attacks, and strokes and were considered safer for women.
- 18. During the 1990's, new "third generation" progestins were developed. Unfortunately, these "third generation" progestins (e.g. gestodene and desogestrel) have been associated with a greater risk of blood clots in the deep veins (deep vein thrombosis or "DVT") and lungs (pulmonary embolism or "PE"). As a result of this increased risk of blood clots, the FDA has required that products containing third generation progestins include a Warning of the potentially increased risk of thrombosis.
- 19. Yasmin and Yaz contain the same estrogen component, ethinyl estradiol, that has been used in the lower dose birth control pills for decades.
- 20. However, drospirenone is a new type of progestin and is considered a "fourth generation" progestin. No other birth control pills contain drospirenone, except for a recently approved generic version of Yasmin and Yaz marketed under the trade name Ocella.

- 21. Since drospirenone is new, there are not decades of data available to support its safe use as there are with second generation progestins. Studies that were done prior to FDA approval, however, indicate that drospirenone has certain effects that are different from those of traditional second generation progestins, and potentially more dangerous.
- 22. One possible mechanism of action is that drospirenone interacts differently with ethinyl estradiol compared to other progestins, such that it does not sufficiently counterbalance the clotting effects of estrogen as do other progestins, particularly the second generation progestins.
- 23. Another possible mechanism of action is that drospirenone causes an increase in potassium levels in the blood, which can lead to a condition known as hyperkalemia if the potassium levels become too high.
- 24. Hyperkalemia can cause heart rhythm disturbances, such as extrasystolies, pauses, or bradycardia. If left untreated, hyperkalemia can be fatal.
- 25. If hyperkalemia disrupts the normal heart rhythms, the flow of blood through the heart can be slowed to the point that it permits blood clots to form. Blood clots in the heart can then lead to heart attacks, or the clots can break off and travel to the lungs where they can cause pulmonary embolism, or can travel to the brain causing stroke.
- 26. Indeed, during the brief time that Yasmin and Yaz have been sold in the United States, hundreds of reports of injury and death have been submitted to the FDA in association with Defendants' products.
- 27. In April 2002, the British Medical Journal reported that the Dutch College of General Practitioners recommended that older second generation birth control pills be prescribed in lieu of Yasmin as a result of 40 cases of venous thrombosis among women taking Yasmin.

- 28. In February 2003, a paper entitled *Thromboembolism Associated With the New Contraceptive Yasmin* was published in the British Medical Journal detailing a Netherlands Pharmacovigilance Centre report of five additional reports of thromboembolism where Yasmin was suspected as the cause, including two deaths.
- 29. In fact, in less than a five-year period, from the first quarter of 2004 through the third quarter of 2008, over 50 reports of death among users of Yasmin and Yaz have been filed with the FDA.
- 30. These reports include deaths associated with cardiac arrhythmia, cardiac arrest, intracardiac thrombus, pulmonary embolism, and stroke in women in their child bearing years.
 - 31. Some deaths reported occurred in women as young as 17 years old.
- 32. Significantly, reports of elevated potassium levels are frequently included among the symptoms of those suffering death while using Yasmin or Yaz.
- 33. Two recent studies, released in August 2009, have found significantly increased risks of harm associated with Yasmin or Yaz over other types of birth control pills. The first study assessed the risk of developing venous thrombosis in woman who use oral contraception. The woman ranged in age from 15 to 49 and had no history of heart disease or any malignant condition. The study found that of the 3.3 million women taking oral contraceptives, there were 4,213 venous thrombotic events. Of this total, 2,045 occurred in women using drospirenone oral contraceptives. The study concluded that "oral contraceptives with …drospirenone were associated with a significantly higher risk of venous thrombosis than oral contraceptives with levonogestrel." Lidegard, et al., *Hormonal contraception and risk of venous thromboembolism: national follow up study*, The British Medical Journal 2009, 330:B2921.

- 34. The second study found that Yasmin or Yaz users have twice the risk of a clotting event than users of birth control pills that contain levonorgestrel. Vandenbroucke, et al., *The venous thrombotic risk of oral contraceptives, effects of estrogen dose and progestin type: results of the MEGA case-control study,* The British Medical Journal 2009, 339:B2921.
- 35. Despite the wealth of scientific evidence, Defendants have not only ignored the increased risk of the development of the aforementioned injuries associated with the use of Yasmin and Yaz, but they have, through their marketing and advertising campaigns, urged woman to use Yasmin or Yaz instead of birth control pills that present a safer alternative.

Over-Promotion of Yasmin and Yaz

- 36. Defendants market Yasmin and Yaz as providing the same efficacy as other birth control pills in preventing pregnancy, but with additional benefits.
- 37. However, because Yasmin and Yaz contain the fourth generation progestin drospirenone, they present additional health risks not associated with other birth control pills.
- 38. For example, prior to its integration with Defendant Bayer in 2006, Berlex Laboratories promoted Yasmin's fourth generation progestin, drospirenone, by stating, "Ask about Yasmin, and the difference a little chemistry can make."
- 39. In response, on July 10, 2003, the FDA objected to the characterization that drospirenone was a benefit compared to the progestin used in other combined oral contraceptives and issued a warning letter stating, "FDA is not aware of substantial evidence of substantial clinical experience demonstrating that Yasmin is superior to other COCs or that the drospirenone in Yasmin is clinically beneficial. On the contrary, FDA is aware of the added clinical risks associated with drospirenone [.]"

- 40. The FDA's warning letter continued by stating that the advertisement failed "to communicate that the potential to increase potassium is a risk" or that "increased serum potassium can be dangerous."
- 41. More recently, Defendants advertised that its product Yaz was indicated for treatment of premenstrual syndrome or "PMS," as opposed to the less serious condition of premenstrual dysphoric disorder or "PMDD."
- 42. Defendants also advertised that Yaz contained the added benefit of preventing or reducing acne.
- 43. In response, on October 3, 2008, the FDA issued another warning letter to Defendant Bayer for the misleading advertisement, reiterating that the marketing was misleading because it promoted Yaz for medical conditions beyond the limits of the FDA approval, and adding that "Yaz has additional risks because it contains the progestin, drospirenone ... which can lead to hyperkalemia in high risk patients, which may result in potentially serious heart and health problems."
- 44. The FDA further warned in its October 3, 2008 letter that Yaz "does not result in completely clear skin" and that Defendants' "TV Ads misleadingly overstate the efficacy of the drug."
- 45. Indeed, the FDA felt Defendants' overpromotion of Yasmin was so severe that it required Bayer to run new TV advertisements to correct the previous misleading Yaz advertisements regarding acne and premenstrual syndrome.
- 46. Bayer ultimately agreed to spend at least \$20 million on corrective TV advertisements and to submit all Yaz advertisements to the FDA for advanced screening for the next six years.

Plaintiff's Use of Yaz and Resulting Injuries

- 47. As a result of Defendants' claim regarding the effectiveness and safety of Yaz, Plaintiff's medical provider prescribed and Plaintiff began using Yaz in July, 2007. Plaintiff used Yaz until November, 2007, when she was diagnosed with deep vein thrombosis.
 - 48. Plaintiff was hospitalized for those injuries in November, 2007.
- 49. As a direct and proximate result of using Yaz, Plaintiff suffered the injuries described above.
- 50. Prior to Plaintiff's use of Yaz, Defendants knew or should have known that use of Yaz created a higher risk of thrombotic events than other oral contraceptives on the market, including but not limited to second generation oral contraceptives, and that, when taken as directed, such use was unreasonably dangerous to consumers.
- 51. Therefore, at the time Plaintiff used Yaz, Defendants knew or should have known that the use of Yaz created an increased risk to consumers of serious personal injury, including gallbladder disease, deep vein thrombosis, pulmonary embolism, heart attacks, stroke, and even death.
- 52. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of Yaz, Defendants failed to adequately warn Plaintiff and/or her health care providers of said serious risks before she used the products.
- 53. Had Plaintiff and/or her heath care providers known of the increased risks and dangers associated with Yaz, she would not have used the product and would not have suffered a deep vein thrombosis in November, 2007.

- 54. As a direct and proximate result of her use of Yaz, Plaintiff suffered physical injury, including but not limited to, conscious pain and suffering, as a result of her deep vein thrombosis.
- 55. As a direct and proximate result of her use of Yaz, Plaintiff has suffered and will continue to suffer pecuniary losses.
- 56. Plaintiff files this lawsuit within the applicable limitations period of first suspecting that the product Yaz was the cause of any appreciable harm sustained by Plaintiff. Plaintiff could not, by the exercise of reasonable diligence, have discovered the wrongful cause of her injuries at an earlier time because when the Plaintiff's injuries were discovered their cause was unknown to Plaintiff. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, that Plaintiff had been injured, the cause of the injuries, or the tortious nature of the conduct causing the injuries, until less than the applicable limitations period prior to the filing of this action. Additionally, Plaintiff was prevented from discovering this information sooner because Defendants herein misrepresented and continue to misrepresent to the public and to the medical profession that Yaz and Yasmin are safe and free from serious side effects, and Defendants have fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

FIRST CAUSE OF ACTION

Products Liability

Defective Manufacturing

57. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

58. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers

of Yaz.

59. The Yaz birth control pills manufactured, designed, sold, distributed, supplied

and/or placed in the stream of commerce by Defendants were expected to and did reach the

consumer, Plaintiff, without any alterations or changes.

60. The Yaz birth control pill product manufactured, designed, sold, distributed,

supplied and/or placed in the stream of commerce by Defendants, was defective in its

manufacture and construction when it left the hands of Defendants in that the product deviated

from design specification, formula, or performance standards of the manufacturer, such that it

was unreasonably dangerous to an ordinary user or consumer and posed a serious risk of injury

and death.

61. As a direct and proximate result of Plaintiff's use of Yaz as manufactured,

designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff

suffered personal injury, economic and non-economic damages, and will continue to suffer such

harm, damages, and economic loss in the future.

62. Defendants acted willfully or with gross negligence indicating a wanton disregard

for the rights of Plaintiff and others, rendering Defendants liable to Plaintiff for punitive

damages.

SECOND CAUSE OF ACTION

Products Liability

Defect in Design or Formulation

- 63. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.
- 64. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Yaz.
- 65. The Yaz birth control pills manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants were expected to and did reach consumers such as Plaintiff without any alterations or changes.
- 66. The Yaz birth control pill product manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce was defective in design or formulation in that, when it left the hands of Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation, and/or the product was more dangerous than an ordinary consumer would expect.
- 67. The foreseeable risks associated with the design or formulation of the Yaz birth control pill product, include, but are not limited to, the fact that the design or formulation of Yaz is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.
- 68. As a direct and proximate result of Plaintiff's use of Yaz as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.
- 69. Defendants acted willfully or with gross negligence indicating a wanton disregard for the rights of Plaintiff and others, rendering Defendants liable to Plaintiff for punitive damages.

THIRD CAUSE OF ACTION

Products Liability

Defect Due to Inadequate Warning or Instruction and

Inadequate Post-Marketing Warning or Instruction

- 70. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.
- 71. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Yaz.
- 72. The Yaz birth control pills manufactured and supplied by Defendants were defective due to inadequate warning or instruction, because at the time the product left their control Defendants knew or should have known that the product was unreasonably dangerous in that it created a substantial increased risk of serious bodily harm and death to reasonably foreseeable consumers such as Plaintiff, and Defendants failed to adequately warn consumers and/or their health care providers of such increased risk.
- 73. The Yaz birth control pills manufactured and supplied by Defendants were also defective due to inadequate post-marketing warning or instruction, because after the product left their control, Defendants became aware of or in the exercise of ordinary care should have known that the product posed a substantial increased risk of serious bodily harm and death to reasonably foreseeable consumers such as Plaintiff and failed to take reasonable steps to provide adequate warnings or instructions to consumers and/or their health care providers of such increased risk.
- 74. As a direct and proximate result of Plaintiff's use of Yaz as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff

suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

75. Defendants acted willfully or with gross negligence indicating a wanton disregard for the rights of Plaintiff and others, rendering Defendants liable to Plaintiff for punitive damages.

FOURTH CAUSE OF ACTION

Negligence

- 76. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.
- 77. Defendants had a duty to exercise reasonable care in the manufacture, design, sale, distribution, supply, marketing, and/or placement of Yaz into the stream of commerce, including a duty to ensure that its product did not pose a significantly increased risk of bodily harm and adverse events.
- 78. Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of Yaz into interstate commerce in that Defendants knew, or should have known, that the product caused such significant bodily harm or death and was not safe for use by consumers.
- 79. Defendants also failed to exercise ordinary care in the labeling of Yaz and failed to issue to consumers and/or their health care providers adequate warnings of the increased risk of serious bodily injury or death due to the use of Yaz.

- 80. Despite the fact that Defendants knew or should have known that Yaz posed a serious increased risk of bodily harm to consumers, Defendants continued to manufacture and market Yaz for use by consumers.
- 81. Defendants knew or should have known that consumers, such as Plaintiff, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.
- 82. As a direct and proximate result of Defendants' negligence, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.
- 83. Defendants acted willfully or with gross negligence indicating a wanton disregard for the rights of Plaintiff and others, rendering Defendants liable to Plaintiff for punitive damages.

FIFTH CAUSE OF ACTION

Breach of Express Warranty

- 84. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.
- 85. Defendants expressly warranted that Yaz was a safe and effective birth control product.
- 86. The Yaz birth control product manufactured and sold by Defendants did not conform to these express representations because it caused serious injury to consumers who used the product.

- 87. As a direct and proximate result of Defendants' breach of warranty, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.
- 88. Defendants acted willfully or with gross negligence indicating a wanton disregard for the rights of Plaintiff and others, rendering Defendants liable to Plaintiff for punitive damages.

SIXTH CAUSE OF ACTION

Breach of Implied Warranty

- 89. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.
- 90. At the time Defendants manufactured, marketed, sold, and distributed the Yaz birth control product, Defendants knew of the use for which the Yaz product was intended and impliedly warranted the Yaz product to be of merchantable quality, fitness, and safe for such use.
- 91. Plaintiff and her health care provider reasonably relied upon the skill and judgment of Defendants as to whether Yaz was of merchantable quality and safe for its intended use and upon Defendants' implied warranty as to such matters.
- 92. Contrary to the implied warranty, Defendants' product Yaz was not of merchantable quality or safe for its intended use because it was unreasonably dangerous as described herein.
- 93. As a direct and proximate result of Defendants' breach of warranty, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

94. Defendants acted willfully or with gross negligence indicating a wanton disregard for the rights of Plaintiff and others, rendering Defendants liable to Plaintiff for punitive damages.

SEVENTH CAUSE OF ACTION

Negligent Misrepresentation and/or Fraud

- 95. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:
- 96. Defendants are the manufacturers, designers, distributors, sellers or suppliers of Yaz and, while engaged in the course of such business, made representations to Plaintiff and her physician regarding the character and/or quality of Yaz for guidance in their decision to select Yaz for Plaintiff's use.
- 97. Defendants had a duty to disclose material information about serious side effects to consumers such as Plaintiff. Defendants intentionally failed to disclose this information for the purpose of inducing consumers, including this Plaintiff, to purchase Defendants' dangerous product.
- 98. Specifically, Defendants' advertisements regarding Yaz made material misrepresentations to the effect that Yaz was a safe and effective medication, which misrepresentations Defendants knew to be false, for the purpose of fraudulently inducing consumers, such as Plaintiff, to purchase said product. Defendants further misrepresented that their product was just as safe, and just as effective or more effective, than other birth control products on the market.
 - 99. Defendants' representations regarding the character or quality of Yaz were untrue.

In addition, Defendants fraudulently suppressed material information regarding the safety and efficacy of Yaz, including information regarding increased adverse events, pre- and post-marketing deaths, and a high rate of severe adverse event reports compared to other birth control pills. Furthermore, Defendants fraudulently concealed the safety information about the use of drospirenone, the only birth control pill using this ingredient. Drospirenone has several serious side effects that are not seen in other forms of birth control.

- 100. Defendants fraudulently concealed safety issues with Yaz in order to induce physicians to prescribe and induce patients, including Plaintiff, to purchase and use Yaz.
- 101. Defendants had actual knowledge based upon studies, published reports and clinical experience that its product Yaz created an unreasonable increased risk of serious bodily injury and death to consumers, or should have known such information.
- 102. Defendants negligently and/or intentionally misrepresented or omitted this information in its product labeling, promotions and advertisements and instead labeled, promoted and advertised its product as safe and effective in order to avoid losses and sustain profits in its sales to consumers.
- 103. In supplying the false information, Defendants failed to exercise reasonable care or competence in obtaining or communicating information to their intended recipients, including Plaintiff and her physician.
- 104. Plaintiff and her physician reasonably relied to her detriment upon Defendants' misrepresentations and/or omissions in its labeling, advertisements, and promotions concerning the serious risks posed by the product. Plaintiff reasonably relied upon Defendants' representations to her and/or her health care providers that Yaz was just as safe and effective as

other types of oral contraceptives for human consumption and/or use and that Defendants' labeling, advertisements and promotions fully described all known risks of the product.

- 105. As a direct and proximate result of Defendants' negligent and/or intentional misrepresentations or omissions, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.
- 106. Defendants' fraudulent concealment tolled the statute of limitations because only Defendants knew the true dangers associated with the use of Yaz as described herein. Defendants did not disclose this information to the Plaintiff, her prescribing physician, the healthcare community and the general public. Without full knowledge of the dangers of Yaz, Plaintiff could not, through reasonable diligence, discover that she had a valid claim.
- 107. Defendants acted willfully or with gross negligence indicating a wanton disregard for the rights of Plaintiff and others, rendering Defendant liable to Plaintiff for punitive damages.

EIGHTH CAUSE OF ACTION

Violation of Texas Deceptive Trade Practices-Consumer Protection Act (DTPA)

- 108. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.
- 109. The Texas Deceptive Trade Practices-Consumer Protection Act prohibits the use of any deception, fraud, false pretense, false promise, misrepresentation or concealment, suppression or omission of any material fact in the conduct of any trade or commerce and declares such acts or practices as unlawful.
- 110. At all times relevant, Defendants violated the Texas Deceptive Trade Practices-Consumer Protection Act by the use of false and misleading representations or omissions of material fact in connection with the marketing, promotion, and sale of Yaz. Defendants

communicated the purported benefits of Yaz while failing to disclose the serious and dangerous side effects related to the use of Yaz with the intent that consumers, like Plaintiff, and their healthcare providers rely upon the misrepresentations and omissions and purchase or prescribe Yaz.

- 111. As a result of violating the Texas Deceptive Trade Practices-Consumer Protection Act, Defendants caused Plaintiff to be prescribed and to use Yaz, thereby causing severe injuries and damages as previously described herein.
- 112. Defendants acted willfully or with gross negligence indicating a wanton disregard for the rights of Plaintiff and others, rendering Defendant liable to Plaintiff for punitive damages.

WHEREFORE, Plaintiff prays for relief as follows:

- 1. Compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined at trial of this action;
- 2. Medical expenses and other economic damages in an amount to be determined at trial of this action;
- 3. Attorneys' fees, expenses, and costs of this action;
- 4. Treble and/or punitive damages; and
- 5. Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury on all issues so triable.

Dated: <u>April 9, 2010</u>	Respectfully submitted,
	By: <u>/s/ Jane E. Joseph</u>
	Jane E. Joseph (OH Bar No. 0074540) SKIKOS, CRAWFORD, SKIKOS, JOSEPH
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CERTIFICATE OF SERVICE

I hereby certify that on April 9, 2010, I electronically filed the foregoing document with the Clerk of Court using the CM/ECF system which will send notification of such filing to all attorneys of record.

/s/ Jane E. Joseph